



## Nitril-Handschuhe Isofield NS400

pure<sup>11</sup>-Nr.: 1130467, Marke: ISOFIELD

### Eigenschaften

- Marke: ISOFIELD
- Handschuhtyp: Dünnsfilm
- Länge in cm: 40 cm
- Chemikalienbeständigkeit - Typ: Typ B
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Zytostatikageeignet
- Lebensmittelkonformität
- Verpackungsform: Beutel
- AQL (Acceptable Quality Level)-Wert: 1,5
- Im Reinraum hergestellt
- Länge in Inches: 16 In
- Materialzusammensetzung: Reinmaterial
- Rollrand
- Passform Hand: beidhändig
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,17 mm

### Empfohlene Reinraumklassen

ISO 5|6|7|8|9

GMP C|D



## Material

- Nitril

## Verpackung

- 1000STK

## Produktvarianten

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**pure<sup>11</sup>-Nr.: 1130467WHXXL, Nitril-Handschuhe Isofield NS400**

Farbe: Weiß; Größe: XXL / VE: 1000STK

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**pure<sup>11</sup>-Nr.: 1130467WHL, Nitril-Handschuhe Isofield NS400**

Farbe: Weiß; Größe: L / VE: 1000STK

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**pure<sup>11</sup>-Nr.: 1130467WHM, Nitril-Handschuhe Isofield NS400**

Farbe: Weiß; Größe: M / VE: 1000STK

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**pure<sup>11</sup>-Nr.: 1130467WHS, Nitril-Handschuhe Isofield NS400**

Farbe: Weiß; Größe: S / VE: 1000STK

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**pure<sup>11</sup>-Nr.: 1130467WHXL, Nitril-Handschuhe Isofield NS400**

Farbe: Weiß; Größe: XL / VE: 1000STK

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# Isofield NS400

400mm (16") Non-sterile nitrile  
Cleanroom gloves

Last updated **18 Mar 2024**

<b>PRODUCT CODE</b>	<b>REF</b> <b>20340</b>	SMALL MEDIUM LARGE XLARGE XXLARGE	20340S 20340M 20340L 20340XL 20340XXL

## PRODUCT INFO

Non-sterile nitrile Cleanroom gloves  
400mm (16") elbow length  
Ambidextrous  
White colour  
Textured palm & fingers  
Beaded cuff  
Low endotoxin levels  
Tested against a range of chemotherapy drugs  
Complies with EU food-grade regulation (EU) No 10/2011  
IPA resistant ink pouches

## CLEANROOM COMPATIBILITY

ISO Class 4 cleanroom  
ISO Class 5 cleanroom  
Class 10 cleanroom  
Class 100 cleanroom

## QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system  
Processed in a NEBB certified ISO Class 5 cleanroom  
Physical properties comply with European medical glove standard EN 455-2:2015

## APPLICATIONS

Handling of components before and after washing  
Transportation and loading of vials  
Preparation of ointments and creams before filling

## STORAGE & SHELF LIFE

Store in a dry, cool place (<40°C) away from direct sunlight  
Do not expose open cartons to prolonged direct fluorescent light  
Three (3) years from date of manufacture

## PACKAGING

100 gloves per sealed inner PE bag,  
1 inner PE bag per sealed outer PE bag,  
10 outer bags per lined carton (1000 pieces)

## PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.17	6.69	EN 455-2:2015
Palm	0.11	4.33	EN 455-2:2015
Cuff	0.09	3.54	EN 455-2:2015

\* +/- 0.02mm

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	390mm	400mm	EN 21420:2020

STRENGTH PROPERTIES	FORCE AT BREAK	TEST METHOD
Throughout shelf life	≥ 6.0 N	EN 455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	1.5 - Level 2 of 3	EN 374-2:2016

## CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm <sup>2</sup> )	< 1800	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm <sup>2</sup> )	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.031	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO <sub>3</sub> )	0.500	IEST-RP-CC005.4
Phosphate (PO <sub>4</sub> )	0.062	IEST-RP-CC005.4
Sulphate (SO <sub>4</sub> )	0.012	IEST-RP-CC005.4
Sodium (Na)	0.050	IEST-RP-CC005.4
Ammonium (NH <sub>4</sub> )	0.020	IEST-RP-CC005.4
Potassium (K)	0.064	IEST-RP-CC005.4
Calcium (Ca)	0.432	IEST-RP-CC005.4
Magnesium (Mg)	ND	IEST-RP-CC005.4
Zinc (Zn)	ND	IEST-RP-CC005.4

\* ND = Not Detected

## PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	66 min	ASTM D6978-05
Cisplatin	> 240 min	ASTM D6978-05
Cyclophosphamide	> 240 min	ASTM D6978-05
Doxorubicin HCl	> 240 min	ASTM D6978-05
Etoposide	> 240 min	ASTM D6978-05
Fluorouracil	> 240 min	ASTM D6978-05
Methotrexate	> 240 min	ASTM D6978-05
Paclitaxel	> 240 min	ASTM D6978-05
Thiotepa	117 min	ASTM D6978-05

## TECHNICAL PROPERTIES

NORM	TEST REFERENCE	EXPLANATION
Chemical innocuousness	EN ISO 21420:2020	Ensures the gloves do not adversely affect the health of the user. The materials present in the gloves must not release substances that are toxic
Sizing & dexterity	EN ISO 21420:2020 and EN ISO 374-2:2019	Determines sizing compliance and glove dexterity
Air leak & water leak	EN ISO 374-2:2019	Assesses the resistance of the glove to penetration
Chemical degradation	EN ISO 374-4:2019	Determines the resistance to degradation by dangerous chemicals
Chemical permeation	EN 16523-1:2015+A1:2018	Determines the resistance of protective glove materials to permeation by potentially hazardous non-gaseous chemicals
Viral penetration	EN 16604:2004	Assesses the resistance of glove materials to penetration by blood-borne pathogens
Endotoxin test	EN 455-3, USP	Specifies requirements for the evaluation of biological safety for gloves
Permeation based on Chemotherapy Drugs	ASTM D6978-05 (2019)	Assesses the resistance of glove materials to permeation by potentially hazardous chemotherapy drugs
EU type certificate	EN ISO 374-1:2016+A1:2018 Type B EN ISO 374-5:2016 EN ISO 374-4:2019	The applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product
UKCA type certificate	EN ISO 374-1:2016+A1:2018 Type B EN ISO 374-5:2016 EN ISO 374-4:2019	The applicable essential health and safety requirements of PPE Regulation (2016/425) as brought into UK law and amended as a Category III product

## LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	11.3 - 14.9kg	11.3 - 14.9kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	9.3 - 12.9kg	9.3 - 12.9kg
Air freight pallet	Max height: 139cm Layers: 4 Cartons: 24	Max height: 139cm Layers: 4 Cartons: 32
Sea freight pallet	Max height: 170cm Layers: 5 Cartons: 30	Max height: 170cm Layers: 5 Cartons: 40

## DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)  
CERTIFICATE OF ANALYSIS (COA)

View [sample](#) of COC & COA



DECLARATION OF  
CONFORMITY (DOC)

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FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate,  
please [email us](#)

Country of origin: **Malaysia**  
HS Code: 4015199000

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